JUN 0 3 2004

K032767

II. 510(K) Summary of Safety and Effectiveness Information

(Per 21 CFR 807.92)

1. **Submitter:** LILY Medical Supplies Co., Ltd.
No.28-2, Shun Chan Tsan, Chu-Nan, Miao-Li Hsien, Taiwan, 350, ROC

Contact Person: Dr. Ke-Min Jen
Official Correspondent
886-3-5208829 (Tel)
886-3-5209783 (Fax)

2. **Date Prepared:** 2003/8/30

3. **Device Name:**

-Proprietary Name:	LILY Volume Meteric Administration Set, CIB-100ES, CIB-120ES, CIB-150ES
-Common Name:	Infusion Set
-Classification Name:	Set, Administration, Intravascular
- Product code:	FPA,
- Regulation:	880.5440

4. **Predicate Device:**
TUTA Healthcare Burette – In Line (150 mL)(**K023595**)

5. **Device Description:**
The LILY Volume Meteric Administration Set, CIB-100ES, CIB-120ES, CIB-150ES, is a single-use, non-toxic, non-pyrogenic and sterile infusion set to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

6. **Intended Use:**
The LILY Volume Meteric Administration Set is designed to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

7. Substantial Equivalence (SE) and Safety and Effectiveness Information:
A claim of substantial equivalence is made to TUTA Healthcare Burette – In Line (150 mL)(**K023595**). The LILY VOLUME METERIC ADMINISTRATION SET and the TUTA Healthcare Burette – In Line (150 mL) are designed to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

8. Performance Testing:

Bench, biocompatibility, sterility are employed upon submission of this 510(K) premarket notification according to the *Guidance on Premarket Notification for Intravascular Administration Sets* document provided by CDRH/ FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 3 2004

LILY Medical Supplies Company, Limited
C/O Dr. Ke-Min-Jen
Official Correspondent
Roc Chinese-European Industrial Research Society
No. 58, Fu-Chiun Street
Hsin-Chu City, CHINA 300
(TAIWAN)

Re: K032767
Trade/Device Name: Lily Volume Meteric Administration Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 15, 2004
Received: March 22, 2004

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032767

IV. Indications for Use Statement

Applicant: LILY MEDICAL SUPPLIES CO., LTD.

510(k) Number: K032767

Device Name: LILY VOLUME METERIC ADMINISTRATION SET,

CIB-100ES, CIB-120ES, CIB-150ES

Indications for Use:

The LILY Volume Meteric Administration Set is designed to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032767